UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

RICHARD WEST and JOSEPH BRUYETTE, individually and on behalf of a class of similarly situated persons;

Plaintiffs,

v.

MICHAEL SMITH, Vermont Secretary of Human Services, JANE DOE, Vermont Deputy Secretary of Human Services, JAMES BAKER, Interim Vermont Department of Corrections Commissioner, JOHN DOE, Vermont Department of Corrections Health Services Director, in their official capacities, and VITALCORE HEALTH STRATEGIES, LLC,

Defendants.

Case No. 2:19-CV-81-WKS

AMENDED COMPLAINT – CLASS ACTION

AMENDED CLASS ACTION COMPLAINT

Richard West and Joseph Bruyette, on behalf of themselves and others similarly situated, bring this class action lawsuit to ask this Court to require the State of Vermont's corrections officials and their contracted medical provider to end their practice of withholding curative medicine to inmates with chronic Hepatitis C Virus (chronic HCV) for nonmedical reasons. The named Defendants know that chronic HCV is a progressive communicable liver disease, that hundreds of inmates with chronic HCV in their custody are at significant risk of serious harm, and that refusing to provide curative medication to treat the disease is likely to result in bodily and mental suffering, including a severely heightened risk of cancer and death. Providing the curative medicine, a daily oral pill for 8 – 12 weeks, is the standard of medical care and there is no medical justification for denying treatment to the named Plaintiffs or the putative class.

Instead, the Defendants refuse to treat the vast majority of inmates with chronic HCV to save money. The Defendants' policy or practice is cruel and discriminatory. It is also reckless and short-sighted. The Defendants' refusal—for financial reasons—to treat hundreds of inmates creates suffering and greater long-term expense for Vermonters and their government. The Defendants' policy or practice must be enjoined in order to provide the standard curative medicine for the sake of those suffering from a potentially deadly chronic infection, and those who may otherwise be infected in the future.

INTRODUCTION

1. Plaintiffs and the class they seek to represent bring this action to challenge the refusal of the Vermont Agency of Human Services (AHS), Vermont Department of Corrections (DOC), and VitalCore Health Strategies, LLC (VitalCore), to provide lifesaving medication to hundreds of inmates with chronic HCV infection.

2. Plaintiffs and the class they seek to represent have been diagnosed with chronic HCV, a highly communicable disease that scars the liver and can cause, among other things, cancer, portal hypertension, excruciating pain, and death. The Centers for Disease Control (CDC) has identified chronic HCV as an epidemic that constitutes the deadliest infectious disease in America, killing more people each year than the next 60 infectious diseases *combined*, including HIV, tuberculosis, and influenza.

3. The denial or withholding of curative chronic HCV medications is not medically justified. Rather, the Defendants refuse to provide medically necessary treatment to avoid the associated costs.

4. Plaintiffs are inmates in DOC's legal custody who are diagnosed with chronic HCV and for whom the Defendants' policy or practice has denied or withheld medically necessary

curative medicine to treat chronic HCV, as described below, in the Plaintiffs' Motion for Class Certification and the Court's Orders in this matter.

5. Defendants are officials of DOC and AHS and the contracted prison healthcare provider. They are responsible for the systematic denial and failure to provide medically necessary curative medicines to incarcerated individuals in their custody who are diagnosed with chronic HCV.

6. The chronic HCV epidemic disproportionately affects individuals in correctional settings. A 2003 CDC survey estimated that 16% to 41% of the incarcerated population in the United States had been infected with Hepatitis C, and 12% to 35% suffered from a chronic infection. Viewed conversely, estimates have indicated that approximately 30% of all persons with chronic HCV infection in the United States spend at least part of the year in a correctional institution.

7. Starting in 2011, the Food and Drug Administration (FDA) approved a series of breakthrough treatments for chronic HCV—known as Direct Acting Anti-Viral (DAA) medications—that achieve a *de facto* cure in more than 90% of cases. DAA treatment constitutes the medical standard of care for all individuals infected with chronic HCV, except those with a short life expectancy who cannot be remediated with DAA treatment, with transplantation, or by other directed therapy. DAA treatment consists of taking a single pill orally each day for 8 – 12 weeks, depending on specific DAA prescribed.

8. The Plaintiffs, each of whom has a life expectancy of more than one year, have requested DAA treatment from DOC or officials acting on its behalf, including former Defendants Benjamin Watts and Michael Touchette. The Defendants, directly or by their policy or practice, forced the denial of their requests for DAA treatment.

9. As of May 2019, DOC's own data show that over 250 inmates under its care have chronic HCV, and that DOC, without medical justification, refuses or fails to treat the vast majority with DAAs.

10. Defendants' policy or practice denies DAA treatment to hundreds of inmates with chronic HCV based on the Defendants' arbitrary criteria, rather than on the basis of medical rationale. By way of example, inmates can only receive DAAs if they are *certain* to be imprisoned for at least one year from the treatment request. Other inmates outside this category are also denied or prevented from accessing DAAs through unnecessary testing, their alleged refusals to receive DAAs, considerations of disease severity, or punitive or other non-medical reasons.

11. Defendants' alleged reasons for denying or failing to provide DAA treatment are not medically justified; they exist only to spare Defendants the costs of providing DAAs.

12. Defendants' policy or practice shows deliberate indifference to the serious medical needs of the Plaintiffs and the putative class, in violation of their rights. Deliberate indifference may be manifested in several ways, including by "prison doctors in their response to the prisoner's needs" or by other corrections officials "intentionally denying or delaying access to medical care." *Estelle v. Gamble*, 429 U.S. 97, 104–05 (1976). In this case, the Defendants are intentionally denying or withholding necessary medical treatment in a manner that conflicts with the standard of care, for non-medical reasons, and with conscious disregard for the substantial risks of serious harm associated with chronic HCV. Each of the Defendants knows that chronic HCV is a serious and deadly disease, that chronic HCV can cause significant harm even without obvious symptoms, and that DAAs provide a *de facto* cure for chronic HCV.

13. Plaintiffs seek declaratory and injunctive relief, on behalf of themselves and a class of similarly situated individuals, to receive DAA treatment and other medically necessary interventions as required by the U.S. Constitution.

14. The named Plaintiffs have exhausted their administrative remedies or the DOC administrative grievance process has been unavailable to them.

JURISDICTION AND VENUE

15. Plaintiffs bring this action under 42 U.S.C. § 1983, the Eighth and Fourteenth Amendments to the United States Constitution.

16. Jurisdiction is proper under 28 U.S.C. § 1331 and 28 U.S.C. § 1343(a)(3).

17. Venue is proper under 28 U.S.C. § 1391(b)(1) and (2), because the events that gave rise to this cause of action—the formulation and execution of the HCV treatment policy or practice—occurred in Vermont and the Defendants reside in Vermont.

PARTIES

A. Plaintiffs

18. Plaintiff Richard West is an adult man, who was formerly incarcerated under sentence at the Northern State Correctional Facility in Newport, Vermont, where medical care was administered by Centurion. While he was incarcerated, he had a diagnosis of chronic HCV, for which former Defendant Centurion and DOC repeatedly and continuously denied or withheld DAA treatment from him, despite the fact that he was a candidate for DAA treatment under the medical standard of care.

19. Plaintiff Joseph Bruyette is an adult man, currently incarcerated under sentence by DOC and, until 2019, held under a contract in Tallahatchie County Correctional Facility, a private prison facility in Tutwiler, Mississippi. He is in the legal custody and control of DOC. He is currently held in the Southern State Correctional Facility in Springfield, Vermont. He

was formerly diagnosed with chronic HCV. For an extended time period prior to the filing of the Complaint in this matter, DOC and its contractors repeatedly and continuously denied or withheld DAA treatment from Mr. Bruyette, despite the fact that he was a candidate for DAA treatment under the medical standard of care.

20. The Court's March 30, 2020 Order held that Mr. West and Mr. Bruyette had standing to bring this matter and that the claims described herein are not moot.

B. Defendants

21. Defendant Michael Smith, Vermont's Secretary of AHS, is sued in his official capacity. In that capacity, he has oversight and authority over all aspects of the operation, administration, management, and governance of the Department of Corrections, Department of Health, and the Department of Vermont Health Access. He has overall responsibility for the budgets, policies, and practices of each agency—including the delivery of necessary medical care for the serious medical needs of all individuals held in DOC's correctional facilities and contracted correctional facilities. Defendant Smith's predecessor office holder, Al Gobeille, was among the leaders of the Defendants' response to public criticism of their refusal to treat chronic HCV in correctional facilities, communicated with the media and Vermont legislature regarding the policies and practices at issue in this Complaint, personally engaged in policy proposals with other Defendants, engaged stakeholders and others regarding DOC's chronic HCV policy, and was well aware of the failure of the Defendants' current policy or practice. As the lead policymaker, Defendant Smith participates in decisionmaking regarding DOC's chronic HCV policy and has been closely involved in the decision to withhold DAAs from hundreds of inmates. At all relevant times with respect to the actions alleged herein, Defendant Smith, and his former office holders, have acted and will continue to act under color of state law.

22. Former Defendant Martha Maksym was the Deputy Secretary of AHS until her resignation. The Deputy Secretary of AHS officeholder – currently unnamed -- is sued in their official capacity. Defendant Smith has delegated some authority to the Deputy Secretary of AHS to oversee DOC's chronic HCV policy developments and the creation of specific chronic HCV provisions via contract. The Deputy Secretary of AHS has participated in decisionmaking regarding DOC's chronic HCV policy; communicated with medical professionals, stakeholders, and others regarding DOC's chronic HCV policy; and had been closely involved in the decision to withhold DAAs from hundreds of inmates. At all relevant times with respect to the actions alleged herein, the Deputy Secretary of AHS has acted and will continue to act under color of state law.

23. Defendant Doe James Baker, the Interim Commissioner of DOC, is sued in his official capacity. In that capacity, he has oversight and authority over all aspects of the management and governance of DOC, including each Vermont state correctional facility. He has overall responsibility for DOC budget and for ensuring the delivery of necessary medical care for the serious medical needs of all individuals held in DOC's correctional facilities and contracted correctional facilities. As DOC's lead policymaker and final grievance officer, Defendant Baker, on his own and through his predecessor office holder Michael Touchette, helped craft the policy or practice that withholds DAA treatment from hundreds of inmates and has proactively or constructively denied inmates access to DAAs under that policy. Former Defendant Touchette, in both his prior roles as Commissioner of DOC and DOC Deputy Commissioner, was among the leaders of the Defendants' response to public criticism of their refusal to treat chronic HCV in correctional facilities, communicated with the media and Vermont legislature regarding the policies and practices at issue in this Complaint, engaged

other public officials in policy development, and received citations to medical literature showing the failures of the Defendants' current policy or practice. He participated in decisionmaking regarding DOC's chronic HCV policy, communicated with medical professionals and others regarding DOC's chronic HCV policy, and was closely involved in creating the policy that withholds DAA treatment based on non-medical considerations. At all relevant times with respect to the actions alleged herein, Defendant Baker, and his predecessor office holders, acted and will continue to act under color of state law.

24. Former Defendant Benjamin Watts was the Health Services Director of DOC until his resignation. The Health Services Director of DOC officeholder – currently unnamed -- is sued in their official capacity. The Health Services Director of DOC has oversight and authority over the delivery of necessary medical care for the serious medical needs of all individuals held in DOC's correctional facilities and contracted correctional facilities. As a DOC Executive Staff member, former Defendant Benjamin Watts, was delegated policymaking authority and was a grievance officer for health-related matters. Former Defendant Watts participated in developing the policy or practice that withholds DAAs from hundreds of inmates and proactively or constructively denied inmates access to DAAs under that policy. He was directly involved in DOC's response to public criticism of its refusal to treat chronic HCV in correctional facilities, communicated with the media and Vermont legislature regarding the policies and practices at issue in this Complaint, engaged other public officials in policy development, and received citations to medical literature showing the failures of the Defendants' current policy or practice. Former Defendant Watts has participated in decisionmaking regarding DOC's chronic HCV policy, communicated with medical professionals and others regarding DOC's chronic HCV policy, and was closely involved in

creating the policy that withholds DAA treatment based on non-medical considerations. At all relevant times with respect to the actions alleged herein, the Health Services Director of DOC, and their predecessor office holders, acted and will continue to act under color of state law.

25. Defendant VitalCore is the current health care provider/vendor for all in-state DOC facilities. The principal office for VitalCore is in Topeka, Kansas; Defendant VitalCore also has an agent address in Jeffersonville, Vermont. As of July 1, 2020, Defendant VitalCore is DOC's contracted agent for the purposes of carrying out the conduct described herein; Centurion was DOC's prior contracted agent from when the Complaint was filed until VitalCore took over. Because of the transfer of contractual responsibilities, the Court ordered Defendant VitalCore as a substitute for Centurion in the current litigation on October 19, 2020. At all relevant times, Defendant VitalCore has acted and will act under the color of state law.

FACTUAL ALLEGATIONS

A. HCV Is a Highly Communicable Life-Threatening Disease

26. Hepatitis C is a blood-borne infectious disease, which is transmitted through exposure to infected blood. Even a microscopic amount of blood can transmit HCV.

27. Hepatitis C is a growing public health crisis both in Vermont and throughout the United States. Out of every 100 people infected with the Hepatitis C virus, 75 to 85 will go on to develop chronic HCV, which is characterized as a Hepatitis C infection that lasts longer than six months.

28. Chronic HCV is a disease that damages the liver, with the potential to affect multiple other organs and bodily functions. The CDC reports approximately 40% of all those with chronic HCV will develop cirrhosis and more than 5% will develop liver cancer. Accordingly, chronic HCV is the leading cause of liver transplants in the United States. Liver transplants

are painful, carry a significant risk of complications, and are rarely made available to prisoners.

29. Individuals infected with chronic HCV suffer from a range of hepatic (affecting the liver) and extrahepatic (affecting other organ systems) symptoms.

30. A common hepatic manifestation of chronic HCV infection is fibrosis, the formation of scar tissue in the liver. This scarring of the liver ranges from mild to severe, with the most severe form of fibrosis being cirrhosis. As cirrhosis progresses, more scar tissue forms, making it difficult for the liver to function.

31. Advanced scarring of the liver is associated with an increased risk of cancer. Cirrhosis is associated with increased rates of liver transplants and increased risk of death.

32. Once individuals develop advanced liver disease, they must undergo cancer screening at regular intervals for the rest of their lives even after they are cured of their chronic HCV infection.

33. A significant number of persons with chronic HCV who have no or mild fibrosis will progress to cirrhosis in the absence of DAAs.

34. Currently, there is no way to predict which newly infected patients will develop advanced liver disease.

35. Chronic HCV is the most common cause of liver transplants in the United States.

36. Liver damage is only one potentially significant consequence of chronic HCV infection.

37. Chronic HCV may have extrahepatic manifestations that affect other organ systems.

38. Chronic HCV infection is associated with myocardial infarction, diabetes, decreased cognitive function, fatigue, joint pain, depression, sore muscles, arthritis, various cancers, decreased kidney function, certain types of rashes, and autoimmune disease. These extrahepatic manifestations, among others, can occur irrespective of the amount of fibrosis in the liver.

39. Delay in treatment can cause irreversible damage to the liver and other vital organs. Because of the many benefits associated with successful HCV treatment, clinicians following the standard of care treat chronic HCV patients with antiviral therapy with the goal of achieving Sustained Virologic Response (SVR), preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications. SVR status means that the virus becomes virtually undetectable in a patient and is considered to be a *de facto* cure of the infection. *See* U.S. Dep't of Veterans Affairs, *FAQs about Sustained Virologic Response to Treatment for Hepatitis C* (2015), *available at* https://www.hepatitis.va.gov/pdf/sustained-virological-response.pdf.

40. Liver damage and scarring related to chronic HCV infection ("fibrosis") is measured in a variety of methods. In addition to the physical exam and history, medical professionals following the standard of care use a combination of other blood tests and imaging to determine the stage of liver damage caused by HCV.

41. Metavir Fibrosis Score ("fibrosis score") measures the degree of inflammation (activity grade A0 to A3) and the degree of fibrosis (Fibrosis State F0 to F4). A score of F0 represents no fibrosis (no scarring), F1 is portal fibrosis without septa formation (minimal scarring), F2 is portal fibrosis with few septa (intermediate scarring), F3 is numerous septa without cirrhosis (severe scarring), and F4 is cirrhosis. A parallel scale of measurement is known as "Ishak

Stage," named after one of the pathologists who developed it, and it quantifies fibrosis on an ascending scale of 0-6.

42. Metavir Scores can be estimated using noninvasive serological testing as well as transient elastography. Liver biopsy is no longer considered the standard of care for staging liver disease. All measures of liver fibrosis have limitations. Beyond the limitations of the individual modalities of disease staging, it is important to understand that the progression of liver disease is not linear and therefore it is difficult to predict an individual's progression through the stages of liver damage over time.

43. Blood tests can provide an "APRI score" determined from a ratio derived from the level of an enzyme in the blood (AST) compared to the AST levels of healthy persons and the number of platelets in the infected person's blood. "APRI" is an acronym for "AST to Platelet Ratio Index." The APRI score provides useful, but often imprecise, measures of fibrosis or cirrhosis. Generally, the lower the APRI score (in the scientific literature a cutoff of less than 0.5 is often used), the greater the negative predictive value (and ability to rule out cirrhosis), and the higher the value (the scientific literature often uses a measurement of greater than 1.5), the greater the positive predictive value (and ability to rule in cirrhosis); midrange values are less accurate and less helpful. The APRI score has a sensitivity of 0.81 when using an APRI score of 0.5 or higher to diagnose fibrosis (defined as a Metavir stage F2 to F4 and Ishak stages 3 to 6 or equivalent). However, a cutoff of 0.5 would fail to identify 19% of people who actually had fibrosis.

44. Another method of estimating fibrosis using blood testing is known as "Fibrosis-4" or "FIB-4." It similarly provides useful but often imprecise measures of fibrosis and cirrhosis. FIB-4 scores estimate liver scarring through a calculation including patient age, platelet count,

and liver enzymes. The FIB-4 score threshold of 1.45 or higher correlates to Metavir Score of F3 or F4, meaning that the threshold is targeted to identify those with advanced fibrosis, to the exclusion of individuals at Metavir Fibrosis Scores F0 through F2.

45. Chronic HCV constitutes a serious medical need, regardless of the stage of fibrosis or disease severity. In recent years, several federal courts have reached analogous conclusions. *See, e.g.*, *Hill v. Palmer*, No. 1:18-cv-293-FDW, 2019 WL 956816, at *1-*2, *7-*8 (W.D.N.C. Feb. 27, 2019); *Workman v. Atencio*, No. 1:16-cv-00309-BLW, 2018 WL 4496628, at *4 (D. Idaho Sept. 19, 2018); *Chimenti v. Pa. Dep't of Corr.*, Civil Action No. 15-3333, 2017 WL 3394605, at *7 (E.D. Pa. Aug. 8, 2017); *Christy v. Robinson*, 216 F. Supp. 2d 398, 413 (D.N.J. 2002).

46. Defendants' policy or practice denies necessary and standard medical care for chronic HCV, causing serious bodily and mental harm, as well as creating immediate and substantial risks to the health of Plaintiffs and those similarly situated, including risks of irreparable liver damage, cancer, and death.

B. The Hepatitis C Epidemic Is a Widespread, Growing Crisis Hepatitis C is rapidly spreading throughout Vermont, the United States, and the world.

48. For many individuals who suffer from chronic HCV, the origins of their infection are unknown. Before 1992, when widespread screening of the blood supply began in the United States, chronic HCV was commonly spread through blood transfusions, organ transplants, and contact with unsterilized medical equipment.

49. More recently, the opioid epidemic has exacerbated chronic HCV prevalence. New cases of chronic HCV are disproportionately among people who inject drugs, including people who were using oral prescription opioids and turned to injection of opioids and heroin. Newly

reported cases of chronic HCV have also been increasing among younger people as a result of the opioid epidemic. *See* Press Release, CDC, Increase in hepatitis C infections linked to worsening opioid crisis (Dec. 21, 2017), *available at* https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html.

50. It is widely accepted that the number of reported cases of Hepatitis C nationwide understates its actual prevalence. Addressing viral hepatitis generally, the United States Surgeon General has declared a "silent epidemic," and estimated that as many as 5.3 million Americans were affected. *See* Regina M. Benjamin, *Raising Awareness of Viral Hepatitis: National Hepatitis Testing Day*, 127 Pub. Health Rep. 244, 244 (2012), *available at* https://www.cdc.gov/hepatitis/pdfs/surgeongeneral-phr_may-june2012.pdf. With respect to Hepatitis C specifically, estimates are that nearly 3.5 million Americans are infected. *See* Vt. Dep't of Health, *Hepatitis C*, http://www.healthvermont.gov/disease-control/hep-c (last visited May 15, 2019).

51. The Vermont Department of Health acknowledges that Hepatitis C surveillance is particularly challenging in light of the CDC's estimate that up to 50% of people living with the infection in the United States are unaware of their own infection. The Department of Health's surveillance estimates thus do not reflect the many Vermonters, and thus many incarcerated individuals, who are likely infected with HCV but unaware of their status. *See* Vt. Dep't of Health, *HCV Surveillance*, http://www.healthvermont.gov/immunizations-infectious-disease/hepatitis-c/surveillance (last visited May 15, 2019).

52. The Vermont HCV surveillance data that do exist show a significant rise in annually reported new cases throughout the past six years, from 541 infected individuals in 2010 to 928

infected individuals in 2016. *See* Declaration of James Diaz, ECF No. 1-1, Exhibit 1 at PRR-002112. In 2017, HCV was the second most common newly reported disease in Vermont and "one of the greatest disease burdens across the state." *Id.* at PRR-002106. CDC data indicate that there were 723 new cases of HCV reported in 2016 alone.

53. The Hepatitis C epidemic disproportionately affects individuals in correctional settings. Of the 2.2 million people in American jails and prisons, the CDC estimates that approximately one-third of them are infected with chronic HCV.

54. In its January 2018 report, the Vermont Department of Health estimated 150 – 879 cases of HCV among inmates in the custody of DOC. ECF No. 1-1, Exhibit 1 at PRR-002107 Table A.

55. In 2016, the estimated mortality rate in Vermont for HCV was 6 deaths for every 100,000 Vermonters; 35 people died in Vermont as a result of HCV. *See* HepVu, *Local Data: Vermont*, https://hepvu.org/state/vermont/ (last visited May 15, 2019).

56. HCV is typically diagnosed through a blood test that reveals HCV antibodies. Guidelines from the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America—which articulate the current standard of care for HCV screening—recommend screening certain populations based on demography, prior exposures, behaviors, and medical conditions. This screening increases the likelihood of early detection and reduces the risk of liver cancer, death, and transmission to others.

57. The same guidelines recommend screening of all persons who have ever been incarcerated. The CDC recommends screening all persons born between 1945 and 1965 and anyone who has ever injected drugs.

58. According to DOC, it began offering HCV testing at intake in 2015. However, DOC

officials have not answered questions regarding how many inmates who entered before 2015 have been tested for HCV. Therefore, current DOC data showing 250-300 chronic HCV-positive inmates in custody may be an undercount.

C. Chronic HCV Can Now Be Effectively Cured

59. Prior to 2011, the recommended treatment options for chronic HCV were accompanied by significant adverse side effects, including liver failure, memory loss, and death.

60. In 2011, the FDA approved the first wave of DAAs for the treatment of chronic HCV, and specialists heralded "the beginning of the end of chronic HCV."[1] In 2014, the FDA approved new DAA medications, including Harvoni, Sovaldi, and Olysio. The FDA designated DAAs a "breakthrough therapy,"[2] a classification reserved for drugs that provide substantial improvement over available therapies for patients with serious or life-threatening diseases.

61. DAAs are easily tolerable with mild and treatable side effects and can effectively cure nearly all patients using a course of oral medication taken as one pill once a day over the course of 8 –12 weeks.

62. DAAs are the only medical intervention for chronic HCV that produce an SVR in more than 90% of patients.

63. The FDA-approved DAAs are supported by multiple well-designed, controlled studies

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[1] Marie-Louise Vachon & Douglas T. Dieterich, *The Era of Direct-acting Antivirals Has Begun: The Beginning of the End for HCV?*, 31 Seminars in Liver Disease 399, 399 (2011), *available at* https://www.medscape.com/viewarticle/756591_1.

[2] "Breakthrough therapy" is a term of art used by the FDA for drugs that treat a serious or life-threatening disease, where preliminary clinical evidence indicates that the drug may demonstrate a substantial improvement over existing therapies. *See* 21 U.S.C. § 356(a) (defining "breakthrough therapy" and the process for expedited approval of such drugs under the Federal Food, Drug, and Cosmetic Act).

or well-designed experimental studies.

64. In addition to the curative benefits of DAAs to the patient herself, individuals who achieve SVR are no longer able to transmit the virus to others, thereby curbing the epidemic of HCV infections.

65. The FDA has approved DAA use for nearly all patients with chronic HCV regardless of disease stage or severity.

D. DAA Treatment Is the Standard of Care for Nearly All People with Chronic HCV

66. The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) jointly publish treatment guidelines that establish the national standard of care for HCV treatment.

67. The AASLD and IDSA recommend treatment for all patients with chronic HCV infection—regardless of fibrosis score—except for those with a short life expectancy that cannot be saved by DAA treatment, liver transplantation, or another directed therapy. *See* AASLD/IDSA, *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C* (updated May 24, 2018), *available at* https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/HCVGuidance_May_24_2018b.pdf.

68. The Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicaid, has emphasized the importance of access to DAAs for Medicaid beneficiaries. On November 15, 2015, CMS issued guidance (CMS Notice), advising state Medicaid agencies to include DAAs in their coverage of outpatient prescription drugs and warning against impermissible restrictions. Ctrs. for Medicare & Medicaid Servs., *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs* (Nov. 5, 2015),

https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf. Addressing itself to the Medicaid Act, the CMS Notice observed "some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs." The CMS Notice cited as examples of these improper limitations the requirement of a minimum fibrosis score, drug or alcohol abstinence, and that DAAs be prescribed by specialists.

69. The CDC endorses the use of these effective medications to reduce HCV infection and transmission rates, thereby enhancing public health and lowering treatment costs to the state in the long run. Medicare and the U.S. Department of Veterans Affairs also utilize coverage criteria consistent with the standard of care, as per AASLD/IDSA guidelines.

70. The Vermont Department of Health Access (DVHA) adopts guidelines for delivery of medical care to residents enrolled in Dr. Dinosaur and the Vermont Health Access Plan, which are both subsidized medical insurance plans available to low-income Vermonters (ultimately funded in part by Medicaid). DVHA's guidelines for treatment of chronic HCV allow for coverage of DAA treatment consistent with the standard of care, and without regard to fibrosis score, disease severity, or other non-medical factors, as per AASLD/IDSA guidelines.

71. After previously lowering the fibrosis score requirement in an incremental policy change, on October 24, 2017, the Vermont Medicaid's Drug Utilization Review Board, the relevant department of DVHA, abolished the fibrosis score and sobriety restrictions altogether that had prevented Vermont Medicaid patients from accessing DAA treatment consistent with the standard of care. On December 4, 2017, DVHA sent an advisory update to Medicaid providers indicating curative DAA treatment must be accessible without regard to fibrosis

score or sobriety requirements. *See* "Dear Medicaid Provider" Letter from Nancy Hogue, B.S., Pharm. D., Director of Pharmacy Services of the Department of Vermont Health Access (Dec. 4, 2017), *available at* http://dvha.vermont.gov/for-providers/hepatitisc-fibrosisrestrictionchanges-final.pdf/view (also attached to ECF No. 1-1 as Exhibit 15). Vermont Medicaid is also under the direction of Defendants Smith and the Deputy Secretary. Former named Defendants Touchette and Watts were made aware of this policy change, as was former Defendant Centurion.

72. The payors, medical associations, and organizations described herein rely on evidence-based research that shows refusing or withholding treatment has a variety of adverse effects, including risk of irreversible liver damage, a heightened risk of cancer and other adverse health outcomes, as well as an increased risk of death. For example, one study showed that withholding DAAs until patients reach a fibrosis score of 3 or 4 results in a two-to-three times higher rate of liver-related mortality in HIV positive patients, compared with commencing DAA treatment when the score is F2. *See* Cindy Zahnd et al., *Modelling the Impact of Deferring HCV Treatment on Liver-related Complications in HIV Coinfected Men Who Have Sex With Men*, 65 J. Hepatology 26, 26 (2016), *available at* https://www.journal-of-hepatology.eu/article/S0168-8278(16)00164-1/pdf.

73. Withholding treatment can also increase psychological stressors including anxiety, illness uncertainty (the inability to determine the meaning of illness-related events), and depressive symptoms. With treatment, patients who are cured of chronic HCV report an improvement in their mental well-being.

74. Defendants' public statements suggest that they generally agree that DAA treatment is efficacious and constitutes the standard of care. *See* ECF No. 1-1, Exhibit 2 at PRR-001719 &

n.1.

75. When Defendants deny or withhold potentially lifesaving treatment to Plaintiffs and others similarly situated, they fail to follow the standard of care according to the CDC, AASLD, IDSA, CMS, Medicare, the U.S. Department of Veterans Affairs, most commercial health insurers, and Vermont Medicaid.

E. The Defendant's Policy or Practice Unconstitutionally Denies to or Withholds from Plaintiffs and the Putative Class Treatment for Chronic HCV

1. Vermont Law

76. Vermont law requires DOC to meet its constitutional obligation to ensure inmates receive health care consistent with "prevailing medical standards" while in custody. *See* 28 V.S.A. § 801(a) ("The Department *shall* provide health care for patients in accordance with the prevailing medical standards . . . .") (emphasis added). The statute requires that DOC "establish and maintain" policies for the delivery of such care. *See id.* § 801(d).

77. DOC accordingly adopted "Policy 351" in 1986. In its 2017 iteration, Policy 351 provides that healthcare services for all Vermont inmates "shall be administered in a humane and professional manner, with respect to inmates' constitutional rights to healthcare and protection from cruel and unusual punishment." *See* ECF No. 1-1, Exhibit 3 at PRR-000152. DOC acknowledged that in order to administer medical care consistent with this standard, it or its agents shall ensure all inmates have access to "professional medical, mental health, and dental care in accordance with the prevailing medical standards." *Id.* DOC conducts diagnostic HCV confirmatory testing within seven days of admission and also provides inmates a medical assessment within fourteen days. *See* ECF No. 1-1, Exhibit 2 at PRR-001719.

78. The statute further requires that DOC provide inmates access to medical treatment outside its prison facilities, if required under the standard of care. *See* 28 V.S.A. § 801(a).

79. The statute also obligates DOC to "immediately" secure medical care for any inmate who "is in need of medical care." *See id.* § 801(c).

80. Finally, the statute defines health care services that are "medically necessary." *See id.* § 801(e)(5)(A). These are "services that are appropriate in terms of type, amount, frequency, level, setting, and duration to the individual's diagnosis or condition, are informed by generally accepted medical or scientific evidence, and are consistent with generally accepted practice parameters." *Id.*

81. Such services are specifically required to be informed by the need to "prevent the onset or worsening of a health condition." *Id.*

2. The Defendants' Recent Policy or Practice of Rationing and Denying DAA Treatment

82. DOC has legal custody and is responsible for the medical care of both pre-sentence detainees and individuals who are serving sentences in Vermont-based or contracted-for correctional facilities following criminal conviction. Plaintiffs identify these individuals collectively as "inmates."

83. Until fall 2018, the Defendants' position on DAA treatment for chronic HCV was exclusively set forth in a Centurion-authored document entitled "Management of Hepatitis C" (Centurion Guidelines). *See* ECF No. 1-1, Exhibit 4. The Centurion Guidelines acknowledge that liver scarring from chronic HCV can place an inmate at risk for "several serious symptoms/complications, as well as liver failure or liver cancer." *Id.* at PRR-000195.

84. Under the Centurion Guidelines, only one person with chronic HCV was provided DAAs in 2017.

85. The Centurion Guidelines require that inmate patients who suffer from chronic HCV undergo testing to receive a "fibrosis score" before they may receive DAA treatment. Those who receive a score of F0-F1 are excluded from DAA treatment altogether, in conflict with the standard of care. Those who receive a score of F2-F3 are eligible to receive treatment within twelve months, but there are multiple barriers to treatment in the guidelines.

86. The Centurion Guidelines require that an inmate with a score of F2 – F3 have 12 – 18 months remaining on their sentence before qualifying for treatment. Centurion claimed that this is so that the entire course of treatment may be completed within the prison. Centurion's own policy, however, acknowledges that treatment takes far less time to complete. Under this policy or practice, individuals in DOC's legal custody who have yet to receive a criminal sentence are categorically excluded from treatment.

87. The standard of care does not require patients to stay at a hospital or medical facility for 12 – 18 months in order to receive DAA treatment. Medical supervision for the treatment, which consists of taking a pill once per day for 8 – 12 weeks, can be accomplished in the community with a primary care physician.

88. Further, the Centurion Guidelines state that "[p]atients have a responsibility to learn from past behaviors and interact with society positively." *Id.* at PRR-000198.

89. The standard of care for chronic HCV does not include any consideration of whether patients "interact with society positively" in order to receive lifesaving medical care.

90. The Centurion Guidelines also require that an inmate with a score of F2-F4 not have "chronic disciplinary issues" in order to receive treatment. *Id.* at PRR-000202. What constitutes "chronic" is undefined, as is the seriousness of the "issue" that would forestall treatment. In other words, if an inmate keeps getting in fights or sells too many cigarettes,

access to life-saving treatment may be denied. Under the Centurion Guidelines, it appears that a tendency to argue with correctional officers, or use curse words, or write nasty letters could also be a basis to deny lifesaving treatment. Such considerations conflict with the standard of care.

91. The Centurion Guidelines have also historically excluded from treatment individuals "who have not been clean/sober for at least 12 months prior to treatment initiation and/or with new tattoos." ECF No. 1-1, Exhibit 26 at PRR-000304. The standard of care for chronic HCV excludes sobriety requirements and does not include any such considerations regarding tattoos.

92. On July 1, 2020, Defendant VitalCore took over Centurion's responsibilities by entering into a contract to provide health care for individuals in DOC's legal custody. Like the Centurion Guidelines before it, the DAA treatment policy reflected in the VitalCore contract employs a disease severity threshold (FIB-4 score of 1.45 or greater needed in order to request a FibroScan that precedes treatment) and ambiguous length of custody restriction that are inconsistent with the standard of care, with the result that VitalCore's policies or practices leave many class members excluded from DAA treatment.

3. The Defendants Know Chronic HCV Is a Serious Medical Condition that Places Inmates at Substantial Risk of Harm, but Deny or Withhold Treatment Anyway

93. In 2018, Vermont Legal Aid's Health Care Advocate (HCA) began asking the Defendants about their treatment of Vermont inmates with chronic HCV. *See* ECF No. 1-1, Exhibit 5.

94. In April 2018, former DOC Health Services Director Benjamin Watts and Centurion's Regional Director of Health Stephen Fisher made a presentation to the Vermont Hep C Task Force. During this presentation, Dr. Fisher stated with regard to DOC: "We don't treat everybody who has Hep C, for a variety of reasons. What we're shooting for are the people

who have an F2 score or worse." Dr. Fisher also confirmed that in order to be eligible for treatment, the individual needed to be a sentenced inmate with greater than one year of time remaining before release. In other words, individuals in DOC's legal custody who are detained awaiting trial or sentencing are categorically ineligible for HCV treatment, as are many sentenced individuals who may have less than one year remaining until their release.

95. The Defendants provided the HCA with the Centurion Guidelines and treatment data evidencing a near-total neglect of chronic HCV in Vermont's correctional settings. *See* ECF No. 1-1, Exhibit 6 at PRR-002258.

96. On June 21, 2018, in reaction to the HCA's request for information, former DOC Health Services Director Watts highlighted the "financial projections" and costs of DAA treatment in the course of internal messages to former DOC Commissioners Touchette and Lisa Menard. *See* ECF No. 1-1, Exhibit 7 at PRR-001525-27. The response to the HCA's request indicated that DOC had treated only one individual for chronic HCV during all of 2017.

97. In the following months, media reports and political pressure mounted regarding the lack of DAA treatment in Vermont's correctional facilities. *See* Alicia Freese, *Few Vermont Inmates Receive Hepatitis C Treatment*, Seven Days (Sept. 20, 2018), *available at* https://www.sevendaysvt.com/OffMessage/archives/2018/09/20/few-vermont-inmates-receive-hepatitis-c-treatment; Alan J. Keays, *Lawmakers find treatment 'appalling' of hepatitis C inmates* (Sept. 21, 2018), *available at* https://vtdigger.org/2018/09/21/lawmakers-find-treatment-appalling-hepatitis-c-inmates/.

98. Despite public criticism and political pressure, the Defendants did not publish an updated chronic HCV policy. Regardless, the public and written statements of former named

Defendants Gobeille, Maksym, Touchette, and Watts show a clear understanding of the seriousness of chronic HCV infections and the medical standard of care for treating chronic HCV, as well as knowledge of DOC's policy or practice and knowledge that approximately 200 individuals, if not more, will be categorically ineligible for DAAs without medical justification under the Defendants' policy or practice.

99. As of July 18, 2018, the Defendants determined that they would only treat approximately 62 inmates, making about 200 others categorically ineligible for DAAs. On July 18, 2018, former DOC Commissioner Lisa Menard sent former named Defendants Gobeille, Touchette, and Watts an email stating that due to unnamed public health and patient safety concerns, "only inmates that are known to be in custody for the entire duration of the treatment regimen will be provided with treatment." ECF No. 1-1, Exhibit 8 at PRR-001679-70.

100. In July 2018, former named Defendants Gobeille and Watts, if not others, received email messages confirming their policy or practice of restricting access to DAAs to those inmates who were certain to be in DOC custody for at least "46 weeks." ECF No. 1-1, Exhibit 9 at PRR-001534.

101. On October 23, 2018, former Secretary Gobeille wrote a letter to the Vermont Legislature's Joint Legislative Justice Oversight Committee. The letter describes DOC's process for responding to inmates with chronic HCV. Although noting that the standard of care is to wait six months before treating *newly* diagnosed HCV patients, the former Secretary stated that DOC treats all inmates who self-report HCV and receive subsequent testing as "newly diagnosed," even if circumstances make clear that the individual was infected long before. *See* ECF No. 1-1, Exhibit 10 at PRR-001719.

102. In the letter, the former Secretary explicitly described the Defendants' policy as excluding treatment for hundreds of inmates with chronic HCV. Without describing how long the Defendants required an inmate to certainly be in custody to be eligible for DAAs, former Secretary Gobeille estimated that of the monthly average 250 inmates with chronic HCV in Vermont legal custody, there were only "approximately 62 patients that have HCV and will be in DOC custody long enough to receive a course of treatment." *See id.* at PRR-001720.

103. And, while claiming that the Defendants' treatment process was "the same as in the community" and had "nothing to do with funding availability," former Secretary Gobeille notified the committee that he was seeking an appropriation of $2,000,000 to provide DAAs for the approximately 60 inmates with chronic HCV eligible for treatment, having noted that that the remaining almost 200 inmates were categorically ineligible. *See id.* at PRR-001719-21

104. The Vermont legislature appropriated $2,000,000 to DOC for fiscal year 2019 for chronic HCV treatment.

105. In an earlier email from former Secretary Gobeille to former named Defendants Maksym, Touchette, and Watts regarding the $2,000,000 to be appropriated, the former Secretary stated that "I want to personally understand, and I want to personally decide how we spend this money." ECF No. 1-1, Exhibit 11 at PRR-001472.

106. On November 8, 2018, former named Defendants Touchette and Watts testified before the Vermont Legislature's Joint Legislative Justice Oversight Committee.

107. Touchette and Watts, as well as then-Commissioner Menard, testified that the Defendants' policy or practice was to deny DAAs to inmates who might leave DOC custody within some period of time. They did not specify a period of time.

108. Former named Defendants Touchette and Watts, as well as then-Commissioner

Menard, testified that the Defendants' policy or practice did not have a fibrosis-level requirement as part of their DAA eligibility criteria. However, Defendants' documentation and testimony from the same time period indicated inmates were categorically ineligible for DAA treatment if they had a FIB-4 score less than 1.45. Since FIB-4 scores are a predictive measurement of advanced fibrosis, and a FIB-4 score of more than 1.45 correlates to a Fibrosis score of F3 or F4, the documents and testimony indicate that Defendants maintained a proxy fibrosis requirement. *See* ECF No. 1-1, Exhibit 24 at PRR-003488 ("FIB-4 of < 1.45 indicates a negative predictive value for advanced fibrosis, and the plan is generally to recheck the FIB-4 in 4-6 months."); *see also* ECF No. 1-1, Exhibit 25. The standard of care for chronic HCV does not countenance disease severity thresholds for treatment of any type.

109. During testimony, Senator Tim Ashe quoted direct correspondence from Dr. Andrew Hale, the UVM Infectious Disease doctor who consults with the Defendants regarding treatment. In an October 24, 2018 email to Senator Ashe, Dr. Hale wrote that his experience with the Defendants' practice was that they actually did have fibrosis-level requirements, limiting DAA treatment to inmates at F2 or above.

110. On December 12, 2018, former named Defendants Touchette and Watts again testified before the Vermont Legislature's Joint Legislative Justice Oversight Committee.

111. The HCA also testified, stating that the AASLD and ISDSA guidelines refer to FIB-4 testing as a fibrosis-level screening tool that is not "sensitive enough to rule out substantial fibrosis."

112. Afterwards, former named Defendants Touchette and Watts, as well as then-Commissioner Menard, further described their DAA treatment policy, again testifying that the Defendants' policy or practice did not have a fibrosis-level requirement as part of their DAA

eligibility criteria. However, Defendants' documentation and testimony from the same time period indicated inmates were categorically ineligible for DAA treatment if they had a FIB-4 score less than 1.45. Since FIB-4 scores are a predictive measurement of *advanced* fibrosis, and a FIB-4 score of more than 1.45 correlates to a Fibrosis score of F3 or F4, the documents and testimony indicate that Defendants maintained a proxy fibrosis requirement. *See* ECF No. 1-1, Exhibit 24, 25. The standard of care for chronic HCV does not countenance disease severity thresholds for treatment of any type.

113. On January 25, 2019, the HCA and former DOC Commissioner Touchette testified before the Vermont Legislature's House Committee on Corrections and Institutions regarding the lack of treatment for chronic HCV for Vermont's inmates.

114. In testimony, with former DOC Commissioner Touchette present, the HCA expressed concern that the Defendants' policy or practice, deeming inmates categorically ineligible because there was not certainty that the inmate would be in DOC custody twelve weeks *after* they completed DAA treatment for post-DAA testing, did not meet the standard of care.

115. The HCA's office also testified regarding the serious physical harm that results from untreated chronic HCV.

116. Then-Commissioner Touchette testified that DOC had sufficient resources to provide chronic HCV treatment to eligible inmates for the current fiscal year, FY19, and that any remaining funds from the appropriated $2,000,000 would no longer be available after July 1, 2019.

117. Then-Commissioner Touchette testified that DOC's policy or practice made the majority of inmates with chronic HCV categorically ineligible for DAAs due to the lack of certainty regarding their custody duration.

118. Then-Commissioner Touchette testified that there is no issue with wait times for ultrasounds to examine inmates' liver damage.

119. In an April 22, 2019 letter to the HCA, former DOC Health Services Director Watts stated that all inmates held out of state "will be scheduled for timely and appropriate treatment . . . with the goal of initiating DAAs." *See* ECF No. 1-1, Exhibit 12. No further information is given. However, former DOC Health Services Director Watts estimated that full courses of treatment would not be completed until at least one year from the date of the letter. The reason for the substantial delay in treating this population is unaccounted for, the reason for the proposed lengthy delay is unknown, and access to DAAs has so far been withheld from numerous out-of-state inmates.

120. Despite recent statements and data suggesting that DOC's policy or practice regarding chronic HCV has marginally improved for a minority of sentenced inmates, the absence of a binding written policy, in concert with the Defendants' current informal policies and abysmal historical practices, illustrate the ongoing utilization of factors that conflict with the standard of care. As of May 2019, DOC estimates indicate that little more than 20% of inmates in Vermont's legal custody with chronic HCV have completed or are receiving DAA treatment.

121. Public developments since the filing of this litigation have not addressed these violations of law. The DAA treatment policy reflected in the July 21, 2020 VitalCore contract employs a disease severity threshold (FIB-4 score of 1.45 or greater needed in order to request a FibroScan that precedes treatment) and ambiguous length of custody restriction that are inconsistent with the standard of care and leave many class members excluded from DAA treatment.

4. Defendants' Current Policy for Chronic HCV Treatment Categorically Denies DAAs to Hundreds of Inmates

122. The Defendants' current policy or practice can be cobbled together from their recent statements and data, as well as produced documents, a draft policy, grievance denials, Centurion documents, and a new contract with Defendant VitalCore.

123. In a March 8, 2019 letter, former DOC Health Services Director Watts described the categories of inmates who are ineligible for DAA treatment due to length-of-custody restrictions: "detainees who may be released at any time by action of the court, meeting their conditions of release, or by posting bail; and sentenced inmates who 1) have minimum release dates that occur before they would be able to complete a full course of treatment; 2) will serve their maximum sentences prior to completing treatment; or 3) have exceeded their maximum sentences, but have not been released."[3] *See* ECF No. 1-1, Exhibit 13 at PRR-003495-96.

124. According to DOC data sheets from March and May 2019, approximately 150 to 200 inmates have been deemed categorically ineligible for DAA treatment. These data sheets, among other sources, also show the Defendants contending that either an "unknown" amount of time remaining on a sentence or detainment, or less than one year remaining until an inmate reaches their minimum or maximum sentence, justifies categorical denial of DAA treatment. This contention amounts to pretext, given that DAA treatment can be completed in 8 – 12 weeks, that it can be completed under the care of a primary care physician in the community, and that adherence and follow-up testing can be accomplished after release.

125. The Defendants' policies or practices have continued to cause harm to class members

[3] In an April 22, 2019 letter, former DOC Health Services Director Watts stated that inmates at F2 or above are eligible for DAAs "regardless of length of stay," but did not account for the fact that neither DOC nor former Defendant Centuriont conducts accurate testing to determine inmates' fibrosis scores. *See* ECF No. 1-1, Exhibit 12. Thus, inmates may be eligible under former DOC Health Services Director Watts's criteria, but never be able to show they are eligible because they are not provided the necessary medical testing.

long after this litigation was filed. Between October 2019 and February 2020, class counsel individually identified to Defendants at least sixteen class members who were being denied DAA treatment, without any meaningful response. ECF No. 63-1.

126. These restrictions, among others,[4] are not medically justified: they exist only to spare the Defendants' agencies further cost or unlawfully impose punitive restrictions on necessary medical treatment. The Defendants' ulterior motive of cost shows that they had a culpable state of mind and that their choice of testing and treatment regimens was intentionally wrong and did not derive from sound medical judgment.

127. The Defendants' ostensible justification for refusing to provide DAAs to individuals who *might* transition to the community during or after receiving DAAs is a concern around "[t]oo [m]any [v]ariables." *See* ECF No. 1-1, Exhibit 14 at 13 ("Unable at present to manage a successful community transition on treatment: Too Many Variables."). DAAs can be prescribed and monitored by primary care physicians throughout Vermont. This is true with respect to Vermont Medicaid as well, where a primary care physician need only consult a specialist before the initiation of DAA treatment. *See* ECF No. 1-1, Exhibit 15. The Defendants have made no meaningful effort to create a continuum of care for inmates exiting custody since reviewing a related Vermont Department of Health-created draft memorandum of understanding in late 2018.

128. Monitoring is not treatment. To the extent that the Defendants' documentation and testimony indicate that DOC has categorically excluded individuals with FIB-4 scores less than

[4] In addition, inmates have complained of being denied treatment outright, being refused treatment until their circumstances placed them outside the Defendants' length-of-custody criteria, only being treated after submitting multiple grievances, being required to submit to unnecessary and repeated diagnostic tests to forestall DAA treatment, and being told they refused treatment when they did not.

1.45 from DAA treatment, instead providing only monitoring and retesting several months later, the Defendants' policy or practice does not meet the standard of care. *See* ECF No. 1-1, Exhibit 24. As one federal court concluded in rejecting a state government's argument that monitoring is suitable for people who have HCV, but show either mild or no symptoms, this argument "does not address the liver damage that enrollees could suffer during this 'monitoring' period." *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *4 (W.D. Wash. May 27, 2016).

F. The Underlying Reason for DOC's Policy or Practice Is Cost

129. In various public pronouncements, representatives of DOC and the State of Vermont have disavowed any notion that cost is the factor motivating its paltry chronic HCV treatment. *See, e.g.*, ECF No. 1-1, Exhibit 2 at PRR-001721 (Former Secretary Gobeille claiming the criteria that result in only about 60 of the 250 chronically infected individuals in DOC qualifying for treatment "has nothing to do with funding availability" while simultaneously seeking $2,000,000 to provide treatment to the approximately 60 infected individuals).

130. Despite such pronouncements, evidence in the public record illustrates that cost has been and is the primary factor driving Defendants' chronic HCV treatment policy or practice and is principally responsible for the limitations that place the Defendants' policy or practice at irreconcilable odds with the standard of care and inmates' constitutional rights.

131. The belief that treatment of all individuals in DOC custody who are diagnosed with chronic HCV is financially infeasible has long been entrenched in the minds of state officials. As far back as 2014, DVHA officials were engaged in discussions with DOC's medical contractor, who told them that "[a]ll costs come directly out of the State of Vermont tax revenues . . . . treating everyone [in DOC custody] would bankrupt the state." *See* ECF No. 1-

1, Exhibit 16 at PRR-000578.

132. The nature of the contractual relationship between DOC and former Defendant Centurion places cost at the center of the treatment decisionmaking. The contract used a "Per Inmate Per Month" rate as a baseline to determine the amount that former Defendant Centurion is to be paid by DOC. To the extent that the Defendants believed that the expansion of the DAA treatment policy and practice threatened to significantly affect the "Per Inmate Per Month" negotiated rate, they had an incentive to limit such treatment.

133. The continued concern over cost prompted DOC to alter their reimbursement structure entirely when they began contracting with Defendant VitalCore. DOC cited changes to their total expenses for DAA treatment, "due to the cost of the medications and number of patients being treated at any given time," in justifying carving out DAAs for HCV treatment.. Instead of receiving reimbursement, Defendant VitalCore is required to "bill back" any DAA treatment they initiate to DOC; the lone other medications carved out of the "Per Inmate Per Month" negotiated rate are buprenorphine and methadone.

134. In 2014, DVHA's leadership showed significant concern about the cost of the breakthrough chronic HCV medications. The concern was so great that a member of the DVHA Drug Utilization Review Board wrote to the Vermont congressional delegation, incorporating edits and comments from DVHA's Medical Director, Deputy Commissioner, and Director of Pharmacy Services: "The solution to the problem of unaffordable drug prices is not within the scope or ability of the DUR Board. I am writing to you to urge you to consider solutions at a state, regional or federal level. The DUR Board creates policies that balance costs with protecting the prescriber-patient relationship. I have no interest in denying drugs like Sovaldi [one form of DAA treatment] to patients who need it." *See* ECF No. 1-1, Exhibit

17 at PRR-000740-411. This letter concerning cost was circulated among DVHA officials and indicates that whatever the standard of care, DVHA was "gravely concerned" about the price of DAA treatment. *Id.*

135. Dr. Scott Strenio, the Medical Director of the DVHA, relayed the financial motivation to deny treatment, and his indifference to the standard of care, in an email to former Defendant Centurion after he learned that Massachusetts had begun to administer DAA treatment to its patients: "Left wing propaganda no doubt, LOL / But really sobriety not a requirement? / Rationing medical care never done before? Really? / Highly unethical? To break the bank for this one disease state? Really? / Ramping up moral outrage? Nice touch. . . . / Maybe Mass has lots more money but we clearly do not have the capacity to go down this road . . . . / am not sure what the benefit of this would be; outside of what we would do if we had the funding we needed. . . . / Thoughts? (other than sending our members to Mass.)." ECF No. 1-1, Exhibit 18 at PRR-000613-14.

136. Internal emails among Vermont officials discussing DOC's budget request in August 2017 illustrate concern about the scope of a proposed $3 million increase. In the context of this discussion, and disregarding the standard of care, these emails reflect the belief that inmates "may wait out progression of disease to determine if treatment is necessary." *See* ECF No. 1-1, Exhibit 19 at PRR-001357; *see also* ECF No. 1-1, Exhibit 20 at PRR-003382 (discussing calibration of numbers of inmates to be treated by DOC in the context of fiscal impact).

137. There is no medical justification for "waiting out" chronic HCV disease progression.

138. In April 2018, former DOC Health Services Director Watts and Centurion's Regional Director of Health Stephen Fisher made a presentation to the Vermont Hep C Task Force, a

group of third parties invested in Vermont's treatment decisionmaking. In the presentation, Watts and Fisher characterized the notion that "[e]verybody has to be treated" as "HCV Mis-Information." *See* ECF No. 1-1, Exhibit 14 at 12. In support of this point, Watts and Fisher cited, *inter alia,* the "[o]ngoing significant financial toxicities" of DAA treatment. *Id.*

139. On June 21, 2018, to support providing a response to the HCA's request for information, former DOC Health Services Director Watts informed former DOC Commissioners Touchette and Lisa Menard about the costs of treating chronic HCV, noting that inmate eligibility for DAAs was limited to those inmates who would be in custody for a minimum of 9 – 13 months. *See* ECF No. 1-1, Exhibit 21 at PRR-001710-11.

140. In a 2018 document entitled "Management of Hepatitis C," former Defendant Centurion states "*Resource challenged systems* may use the combination of proprietary indices and abdominal ultrasound to assess for the presence of F2-F4 hepatic fibrosis." *See* ECF No. 1-1, Exhibit 4 at PRR-000201 (emphasis added).

141. In DOC's FY2019 Budget Presentation to the Governor of Vermont, in a section marked "key budget issues," it claimed that chronic HCV treatment should be expanded to "[a]ll diagnosed cases of Hepatitis C." However, DOC noted that "the process to fully implement these changes may be delayed. Currently, the cost for treatments has averaged above $150,000.00 per patient. . . . The current treatment drug costs are decreasing, and could be as low as $25,000.00 per treatment course, but the expanded treatments could represent a significant increase in costs which are also not budgeted at this time." *See* DOC, FY2019 Governor's Budget Presentation at 49, *available at* http://doc.vermont.gov/about/reports/department-of-corrections-budget-documents/doc-fy19-budget-presentation (last visited May 15, 2019). DOC articulated no other explanation for

why implementation would be delayed apart from the lack of budgeted resources.

142. Internal emails among Vermont officials discussing adjustments to DOC's chronic HCV treatment protocol from June 2018 to November 2018 focus on the cost of DAA medications, the budgetary calculations, and limiting the budget for chronic HCV treatment to what is needed for those inmates who will certainly be in DOC custody for about one year. *See* ECF No. 1-1, Exhibit 22.

143. Inmates and medical providers have known for several years that cost is the primary factor in denying treatment to hundreds of inmates in DOC custody. In 2019, DOC/Centurion medical providers told their patients that they are good candidates for treatment, but treatment is unavailable to them for reasons beyond the provider's control, such as the cost of DAAs.

144. Even if it were appropriate to consider cost as part of the chronic HCV treatment decision, the Defendants' focus on cost neglects two key points. First, there is a growing consensus in the medical literature that treating individuals with chronic HCV with DAAs is cost-effective, with some studies even concluding that DAA treatment is the rare medical intervention that may be cost-saving. Second, the per-treatment cost of DAA treatment has fallen significantly across the market in recent years, making the cost-effectiveness of treatment at all stages of disease severity even more compelling.

ALLEGATIONS BY NAMED PLAINTIFFS

A. RICHARD WEST

145. Richard West is 48 years old. He entered DOC custody in 2005. Since the filing of this lawsuit, he has been released from DOC custody.

146. Mr. West was diagnosed with chronic HCV in 2006. He has a life expectancy of longer than one year. Mr. West's doctor informed him that he was a good medical candidate for chronic HCV treatment with DAAs.

147. Since at least November of 2018, DOC officials have repeatedly denied Mr. West's requests for treatment for chronic HCV.

148. Mr. West experienced chronic conditions associated with chronic HCV, including fatigue, sore muscles, joint pain, nausea, loss of appetite, digestive issues, dark urine, peripheral neuropathy, dry eyes and mouth, fluid retention in his stomach, and abdominal pain. These conditions cause him to suffer on a near daily basis.

149. Mr. West's chronic HCV also caused him great stress and worry. It was extremely difficult for him to know that the disease may be progressively scarring his liver, that curative treatment is available, but the Defendants refuse to treat him.

150. During the time period that the Defendants continued to withhold treatment, Mr. West was exposed to the risk of disease progression, further scarring of his liver, impairing liver function, and putting him at increasing risk of cirrhosis, liver disease, excruciating pain, and death.

151. DOC/Centurion officials refused to treat him because they said they would not have sufficient time to monitor him after his treatment was completed.

152. Mr. West exhausted his administrative remedies.

153. On and before November 15, 2018, Mr. West submitted an informal grievance asking for chronic HCV curative treatment.

154. On and before November 15, 2018, Mr. West submitted to DOC/Centurion healthcare request forms seeking chronic HCV curative medication. Treatment was verbally denied each time.

155. After multiple denials of treatment, on November 15, 2018, Mr. West submitted a formal grievance form asking for chronic HCV curative treatment.

156. Mr. West did not receive a response to his November 15, 2018 grievance, except that in late December 2018, the grievance was returned to him with a handwritten note at the top stating "Medication Denied."

157. On January 6, 2019, Mr. West submitted an appeal grievance form to former DOC Health Services Director Watts to report that he still had not received a response and that chronic HCV curative medication had been denied.

158. On January 9, 2019, former DOC Health Services Director Watts received Mr. West's grievance appeal.

159. On January 22, 2019, former DOC Health Services Director Watts denied this appeal, stating "there is not time to initiate and complete the treatment."

160. On January 27, 2019, Mr. West appealed the decision to deny him chronic HCV treatment to former DOC Commissioner Touchette.

161. Mr. West did not receive a response to his January 27, 2019 appeal to former DOC Commissioner Touchette.

162. When Mr. West went to the medical office on April 3, 2019, the doctors there would not respond to his requests for chronic HCV treatment. Mr. West was told to leave immediately or he would be dragged away.

163. On April 30, 2019, Mr. West went to the medical office and again asked for chronic HCV treatment and was told by a facility medical provider that he would not receive the chronic HCV curative treatment because there is insufficient time left on his sentence and that he was "not sick enough."

164. No medical reason existed to deny Mr. West treatment with DAAs.

165. Defendants, by their policy or practice, refused to treat Mr. West with DAAs prior to the

filing of this lawsuit, constituting deliberate indifference to his serious medical needs.

B. JOSEPH BRUYETTE

166. Joseph Bruyette is a 59-year-old man who is in the legal custody of DOC.

167. Mr. Bruyette is held at Southern State Correctional Facility in Springfield, Vermont.

168. For most of his time incarcerated by DOC, Mr. Bruyette has been placed in out-of-state correctional facilities. Until early April 2019, Mr. Bruyette was incarcerated in Tallahatchie County Correctional Facility in Mississippi.

169. Mr. Bruyette first entered into DOC custody in 1987. His maximum release date is January 18, 2043. Mr. Bruyette has passed his minimum release date.

170. Mr. Bruyette was diagnosed with chronic HCV in 1994 or 1995. His life expectancy is longer than one year.

171. Mr. Bruyette believes he suffered liver scarring and he has experienced several chronic conditions associated with chronic HCV, including fatigue, abdominal pain, difficulty digesting, bleeding hemorrhoids, and loss of appetite.

172. These conditions caused Mr. Bruyette to suffer nearly every day. In addition to Mr. Bruyette's physical pain, his chronic HCV diagnosis caused him stress and worry.

173. Mr. Bruyette's doctor informed him that he is a good medical candidate for chronic HCV treatment with DAAs.

174. Mr. Bruyette requested treatment for chronic HCV, but DOC repeatedly denied that treatment.

175. Mr. Bruyette exhausted his administrative remedies.

176. On January 2, 2019, Mr. Bruyette submitted a grievance form to notify DOC that he had been denied treatment for chronic HCV.

177. Mr. Bruyette did not receive a response to his January 2, 2019 grievance.

178. On February 11, 2019, Mr. Bruyette appealed the non-response to the Corrections Executive seeking treatment for chronic HCV.

179. Mr. Bruyette did not receive a response to his February 11, 2019 grievance.

180. On March 18, 2019, Mr. Bruyette appealed the decision to deny his chronic HCV treatment to former DOC Commissioner Touchette.

181. On April 11, 2019, Mr. Bruyette received a response to his March 18, 2019 appeal letter from the Corrections Executive. On the response form, the "Denied" box was checked. The Executive's findings stated that Vermont inmates at Tallahatchie County Correctional Facility "will be reviewed and triaged for initiation of treatment" and told him to work with the medical team in his Mississippi facility. Mr. Bruyette put in a healthcare request form and received no response.

182. No medical reason existed to deny Mr. Bruyette treatment with DAAs.

183. Defendants, by their policy or practice, have refused to treat Mr. Bruyette with DAAs prior to the filing of this lawsuit, constituting deliberate indifference to his serious medical needs.

CLASS ACTION ALLEGATIONS

184. Plaintiffs incorporate the preceding paragraphs of this Complaint as if fully set forth herein.

185. Plaintiffs seek to certify a class of all persons:

1. Who are, or will be, in the legal custody of the Vermont Department of Corrections regardless of facility location, and
2. Who have been incarcerated for at least 14 days or completed their Initial Healthcare Receiving Screening, whichever occurs first, and
3. Who have been diagnosed with chronic HCV, and are candidates for DAA treatment as per the standard of care, and

4. For whom DAA treatment has been or will be denied or withheld based on considerations that deviate from the medical standard of care, including, but not limited to: time left before release from DOC custody or indefinite release date, a disciplinary record, a history of substance abuse or mental health issues, the acquisition of tattoos while incarcerated, disease severity considerations, or other unnecessary treatment criteria.

186. As a result of Defendants' deliberate indifference to the serious medical needs of the Class, members of the Class are or will be subject to cruel and unusual punishment and deprived of their constitutional and statutory rights.

187. Defendants are able to identify all members of the putative Class.

188. The named Plaintiffs are members of the putative Class.

189. The requirements of Federal Rule of Civil Procedure 23(a) are satisfied:

a. *Numerosity*. The Plaintiff Class is so numerous that joinder of all its members is impracticable. By way of example, as of May 13, 2019, DOC data shows that over 250 inmates in its legal custody were infected with chronic HCV.

b. *Commonality*. Questions of law and fact common to the Plaintiff Class include but are not limited to: (1) whether chronic HCV is a serious medical need; and (2) whether Defendants' policy or practice of not treating their chronic HCV with DAAs constitutes deliberate indifference to a serious medical need.

c. *Typicality*. The claims of the named Plaintiffs are typical of the claims of the Plaintiff Class. The named Plaintiffs have been diagnosed with chronic HCV, are subject to the Defendants' policy or practice concerning chronic HCV treatment and screening, have been denied chronic HCV treatment with DAAs, and are at the same kind of risks of substantial harm as members of the Plaintiff Class.

d. *Adequacy*. The class representatives and class counsel will fairly and

adequately protect the interests of the Plaintiff Class. The class representatives have no conflict of interest with the putative class members and are committed to obtaining declaratory and injunctive relief that will benefit themselves and the Plaintiff Class by ending Defendants' unlawful policy or practice of denying medical care consistent with the standard of care. Named Plaintiffs are represented by experienced counsel who have specialized expertise in civil rights litigation, complex civil litigation, including class action matters, prisoner litigation, and prior cases involving illegal coverage restrictions for chronic HCV treatment.

190. The requirements of Rule 23(b)(2) are satisfied. Defendants have acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole. The injunctive relief sought will end the unlawful policy or practice for all class members, allowing them to receive proper treatment for chronic HCV.

191. Plaintiffs and members of the proposed class have suffered and will continue to suffer grave and irreparable harm unless the Court orders Defendants to provide the safe and effective treatment of chronic HCV with DAAs as described herein.

192. The Court's March 30, 2020 Order certified this class, appointed Mr. West and Mr. Bruyette as class representatives and appointed their attorneys to be Class Counsel. ECF No. 56.

CAUSE OF ACTION

Count I – Eighth and Fourteenth Amendments to the U.S. Constitution via 42 U.S.C. § 1983

Brought by the named Plaintiffs on their own behalf and on behalf of the putative class

193. Plaintiffs incorporate the foregoing paragraphs as though fully contained herein.

194. Defendants' acts and omissions in their respective official capacities have failed to provide adequate medical care according to the clearly established medical standard of care. This deviation from the standard of care constitutes deliberate indifference to the serious medical needs of Plaintiffs and other similarly situated inmates infected with chronic HCV, thereby establishing a violation of U.S. Const. amend. VIII and XIV, for which 42 U.S.C. § 1983 provides declaratory, equitable, mandamus, and legal remedies.

195. Defendants know of and enforce the policies and practices described above. They know of Plaintiffs' and the Plaintiff Class's serious medical needs, but intentionally refuse to provide treatment addressing those needs. Defendants know that failure to treat those serious medical needs has harmed Plaintiffs and the Plaintiff Class and continues to place them at substantial risk of serious harm.

196. Defendants' conscious disregard of the risks facing Plaintiffs and the Plaintiff Class violates all standards of decency and constitutes deliberate indifference to serious medical needs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court issue the following relief:

a. A declaratory judgment that Defendants' policy or practice of denying or withholding DAA treatment from the Plaintiffs and putative class members violates the Eighth Amendment.

b. An injunction ordering Defendants to: (i) formulate and implement an HCV treatment policy that meets the current standard of medical care, including in identifying and monitoring persons with HCV; (ii) treat Plaintiffs and members of the Class with appropriate DAAs; (iii) provide Plaintiffs and members of the Class an appropriate and accurate assessment of their level of fibrosis or cirrhosis, counseling on drug interactions, and ongoing medical care for complications and symptoms of chronic HCV; and (iv) include in any future contract with any entity to which it delegates its responsibility to provide for the medical needs of class members a provision that requires medical treatment consistent with the Court's Order.

c. Any further appropriate injunctions necessary to prevent future violations of Plaintiffs' and the Class's rights.

d. Certify that this action be maintained as a class action with a class definition as set forth herein.

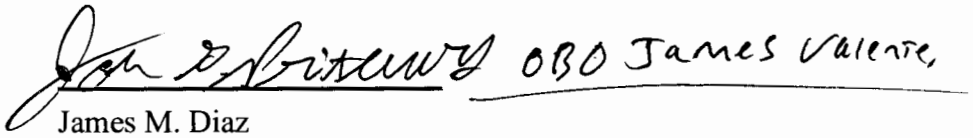
e. Certify Named Plaintiffs identified herein as class representatives and Plaintiffs' undersigned counsel as class counsel.

f. Award Plaintiffs' costs, including reasonable attorneys' fees.

g. Allow any further relief to which Plaintiffs and the Plaintiff Class may be entitled.

Respectfully submitted, this the 9th day of November, 2020.

Attorneys for Plaintiffs



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